EXPERT REPORT

United States and Wisconsin v. NCR Corp., et al.,
Case no. 10-C-0910 (E.D. Wis.)

REPORT ON PUBLIC HEALTH IMPLICATIONS FROM PCB CONTAMINATION IN THE LOWER FOX RIVER, NORTHEASTERN WISCONSIN

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Introduction

At the request of the U.S. Department of Justice, as part of United States and Wisconsin v. NCR Corp., et al., Case no. 10-C-0910 (E.D. Wis.), I have prepared this report in which I evaluate the public health implications from polychlorinated biphenyls (PCBs) sediment contamination in the Lower Fox River in northeastern Wisconsin. To accomplish this, I review and summarize pertinent adverse human health effects of PCB exposure and the public health assessment prepared by the Wisconsin Department of Health and Family Services (DHFS) for the Agency for Toxic Substances and Disease Registry (ATSDR) entitled *PCB Contaminated Sediment in the Lower Fox River and Green Bay, Northeastern Wisconsin* [ATSDR 2006]. Since the primary material reviewed consists of documents from ATSDR, I provide background information on the Agency and the ATSDR Toxicological Profiles and Public Health Assessment processes. This information was mainly gathered from the ATSDR website (www.atsdr.cdc.gov) and from my knowledge of the Agency and its policies and procedures from having worked as a medical officer for ATSDR.

The issues in the case, United States and Wisconsin v. NCR Corp., et al., are related to PCBs found in sediment. Since the primary exposure pathway for humans is through ingestion of fish that have accumulated PCBs in their tissues, I concentrate on health effects related to consuming PCB contaminated fish. While information on the adverse effects of PCBs on animals in the environment is available, this report centers on human health effects; animal studies are discussed only as they pertain to human health.

Agency Background

Overview and mission

The Agency for Toxic Substances and Disease Registry (ATSDR) is a federal public health agency of the U.S. Department of Health and Human Services. The agency is administered together with the National Center for Environmental Health (NCEH), part of the Centers for Disease Control and Prevention (CDC). ATSDR was established by the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA or Superfund) legislation in 1980 to assist in evaluating public health impacts involving hazardous waste sites and to help prevent or reduce further exposures. ATSDR's responsibilities in environmental public heath were reaffirmed and broadened by the Superfund Amendments and Reauthorization Act in 1986.

ATSDR is directed by congressional mandate to perform specific functions concerning the effect on public health of hazardous substances in the environment. These functions include public health assessments of waste sites, health consultations concerning specific hazardous substances, health surveillance and registries, responses to emergency releases of hazardous substances, applied research in support of public health assessments, information development and dissemination, and education and training concerning hazardous substances. ATSDR also receives requests to investigate public health concerns from environmental hazardous releases from other federal, state, and local agencies and from community groups or individual citizens. ATSDR does not have a regulatory role at hazardous waste sites, but it makes public health recommendations to the U.S. Environmental Protection Agency (EPA) and other government agencies concerning hazardous waste sites and releases.

The mission of ATSDR is to "Serve the public through responsive public health actions to promote healthy and safe environments and prevent harmful exposures". ATSDR serves the public by applying the best science, taking responsive public health actions, and providing trusted health information to prevent harmful exposures and disease(s) related to toxic substances.

Organizational structure

ATSDR has historically been organized into four divisions, the Division of Regional Operations (DRO), the Division of Health Assessment and Consultation (DHAC), the Division of Toxicology and Environmental Medicine (DTEM), and the Division of Health Studies (DHS).

DRO has representatives in each of the ten EPA regional offices and Washington, DC. DRO serves as liaison with the other ATSDR divisions and helps facilitate their programs in the regions. The regional offices establish working relationships with the federal and state agencies within the region and work closely with community groups and citizens concerning sites and hazardous chemical health issues. Regional staff prepares or assists in public health assessments, health consultations, or technical assists by reviewing site specific environmental data, epidemiological data, or clinical data. DRO also engages in emergency response and preparedness activities.

The other three divisions within ATSDR are located in the Atlanta, GA headquarters offices. DHAC prepares public health assessments and health consultations on some petitioned sites and Federal facility sites. The division also provides community involvement and health education materials, performs exposure investigations, and oversees the state cooperative agreement program. Among the responsibilities of DTEM are the coordination of activities associated with the Toxicological Profiles and the establishment of the minimal risk levels for hazardous substances. DTEM also provides technical expertise and site-specific support for hazardous material emergency events and chemical specific consultations. DHS contains a health studies investigation branch, a geographic information system group, and a surveillance and registries branch.

ATSDR is undergoing a re-organization and the former four divisions have been restructured as two divisions, pending approval. The proposed Division of Community Health Investigations (DCHI) essentially combines the roles of DRO and DHAC. The proposed Division of Toxicology and Human Health Sciences (DTHHS) combines the functions of DTEM and DHS.

Cooperative agreement program

To expand the capacity on environmental public health efforts at hazardous waste sites, ATSDR, through its Cooperative Agreement Program, currently funds 28 states to perform public health assessments and health consultations, provide technical assistance, perform environmental exposure investigations, and provide community environmental health education activities within their respective jurisdictions. The cooperative agreement partners use ATSDR public health assessment protocols when they evaluate and perform these public health activities.

An ATSDR DHAC (now DCHI) technical project officer is assigned to oversee the activities of the cooperative agreement partner and ensure that the work products are consistent with ATSDR's protocols.

The cooperative agreement partner also works with other ATSDR staff including coordination with the regional offices. The state of Wisconsin, located in Region 5, has a cooperative agreement with ATSDR.

Toxicological Profiles

Toxicological Profile overview and process

ATSDR publishes Toxicological Profiles for hazardous substances commonly found at National Priorities List and other hazardous waste sites. The Toxicological Profiles are available on line from the ATSDR website, by hard copy, and on CD. There are about 300 Toxicological Profiles available. The documents summarize and interpret key epidemiologic, health, and toxicological information available about the specific substance.

The selection of the compound evaluated is based on the frequency found at sites, its toxicity, and the potential for human exposure. Each year there is a ranking process where either new chemicals or an update of a chemical are nominated for review. The number of new studies that have been published on a chemical and budgetary constraints will influence the number of substances evaluated or updated in a given year.

The Toxicological Profiles are developed by a contractor with oversight by an ATSDR Toxicological Profile chemical manager that resides in DTEM (now DTHHS). After being developed, the Toxicological Profile on a given substance goes through ATSDR internal review for consistency and accuracy. The Minimal Risk Level Workgroup reviews the document and makes recommendations for the minimal risk level (MRL) for the specific substance. Three to four external expert peer reviewers also review the draft document. The document is then first released as a Draft for Public Comment (hard copies have a red cover).

After the comment period, as appropriate, the public comments are incorporated into the document and the Toxicological Profile is released as a final document (hard copies have a blue cover). If there are a large number of substantial comments, a second group of external peer reviewers may be asked to review the revised document before the final release. For a few substances, an external panel of experts is assembled to review the document and the public comments prior to the final release as well. The Toxicological Profiles are reviewed and revised periodically. If there had been a substantial number of new studies or information, the Toxicological Profile on a substance may be updated or an addendum may be published.

Structure of the Toxicological Profile

The ATSDR Toxicological Profiles follow a similar format. The first chapter includes the public health statement. The section is in question and answer format and written for the general public to understand. The information in this chapter forms the basis for the Tox FAQs fact sheets available from the ATSDR website. Toxicological Profiles include a summation chapter about relevance to public health. Other chapters include chemical and physical information, production and use, potential for human exposure, analytical methods, and regulations and advisories. The appendices include the minimal risk levels and worksheets.

The bulk of the document revolves around the chapter on Health Effects. This chapter systematically goes through the peer reviewed literature about each type of health effect associated with the substance by route of exposure and length of exposure. Health effects include death, systemic effects, immunological effects, reproductive effects, and cancer. The primary routes of exposure addressed are inhalation, oral exposures, and dermal exposures. Acute (14 day exposures or less), intermediate (15 to 364 day), and chronic (365 days or longer) effects are reported. These sections on health effects include human studies, including case reports and occupational or epidemiologic studies, as well as animal research studies that may be relevant to human exposures. Sections within this chapter also include toxicokinetics, mechanisms of action, sensitive populations, and biomarkers of exposure.

Minimal risk levels (MRLs) and Comparison Values

ATSDR establishes minimal risk levels (MRLs) for specific hazardous substances. They are developed by the ATSDR MRL Workgroup in DTEM (now DTHHS). An MRL is a health guidance level for non-cancer health endpoints. The health endpoints selected are not for serious health effects and are more likely for a subtle clinical finding. Below the MRL, there is no appreciable risk of an adverse non-cancer health effect from daily exposure over the specified time period for the given route of exposure even in sensitive populations. However, the MRL is a screening level and not a health effect level, so environmental media concentrations of a compound that could result in a dose above the MRL would merit further evaluation, but does not mean that an adverse health effect would be present.

The ATSDR MRL Workgroup reviews the health effects information of the toxicological profile to determine if there are sufficient and reliable data to identify the most sensitive non-cancer health effect for acute (14 days exposures or less), intermediate (15 to 364 days), and chronic (365 days or longer) exposures from the oral and inhalation exposure pathways for that substance. ATSDR primarily focuses on studies which include a no observed adverse effect level (NOAEL) for the hazardous substance and prefers human study data, when appropriate. A critical study is identified that is used to establish the MRL. To account for studies that do not include a NOAEL or may be based on animal studies, ATSDR incorporates uncertainty factors into the health guidance level. If there are insufficient data, no MRL will be proposed for the specified exposure route-time frame of exposure for the compound.

After the MRL Workgroup proposes the MRL, both internal and external expert panels review the proposed health guidance value. The public is allowed to comment on the MRL in conjunction with the review of the Toxicological Profile. The MRL and worksheets used to derive the MRL are found in Appendix A of the Toxicological Profile. The MRL may be revised when new information becomes available. MRLs are published on line at: http://www.atsdr.cdc.gov/mrls/mrllist.asp#26tag.

In practice, the MRL is used by DHAC (now DCHI) to generate a Comparison Value for the specific media (soil, drinking water, or air) to which an individual may be exposed. Since oral MRLs are expressed as daily human doses in units of milligrams or micrograms per kilogram per day (mg/kg/day or µg/kg/day), they are not directly comparable with environmental sampling data. Comparison values for soil and drinking water are developed for both child and adult exposures using standard default assumptions on body weight and ingestion rates. The comparison values are then expressed in units of parts per million or parts per billion and can be directly compared to environmental sampling data for soil or drinking water, respectively. Comparison values are not site-specific, but like the MRL, from which

they are derived, can be used by health assessors as an initial health screening guidance value. Comparison values are not regulatory values.

Although MRLs do not address cancer as a health endpoint, ATSDR does include a media specific cancer comparison value for many of the chemicals which are classified by the EPA as known, probable, or possible human carcinogens. For the most part, DHAC (now DCHI) develops these cancer comparison values. ATSDR's Cancer Risk Evaluation Guide (CREG) comparison value uses EPA's cancer slope factor for the chemical, but is calculated using a different exposure time frame. The CREG represents a one in one million increased risk of cancer based on a 70-year exposure to the chemical at that concentration.

Polychlorinated Biphenyls (PCBs) Toxicological Profile

Overview

The *Toxicological Profile for Polychlorinated Biphenyls (Update)* was released as a final version by ATSDR in November 2000 [ATSDR 2000]. This Toxicological Profile follows the standard format and replaced the previous 1997 final version. The hard copy version of the 2000 document includes the word 'update' in the title on the blue cover. On the title page, the hard copy version states that the document was prepared by Syracuse Research Corporation, while the on-line version does not.

The Draft for Public Comment version of the updated Toxicological Profile for PCBs was released in December 1998. An expert panel for the PCB Toxicological Profile convened in September 1999 to review the draft document and the public comments received on the draft document. The summary report from that meeting was prepared in April 2000. The summary report appears in Appendix E of the final version. A four person external peer-review group also reviewed the final document prior to publication. An addendum to the final version was released in April 2011 (see below).

Appendix A of the PCB Toxicological Profile provides MRLs for both an intermediate (14-364 day) and chronic (365 days or longer) duration oral exposure. The intermediate oral MRL of 0.03 µg PCB/kg body weight/day was derived from a monkey study using a PCB congener mixture and a neurological endpoint. The chronic oral MRL of 0.02 µg PCB/kg body weight/day was also derived from a monkey study but used PCB Aroclor 1254 oral exposure and evaluated immunological responses. An uncertainty factor of 300 was used in the derivation of both MRLs to account for the use of a lowest observed adverse effect level (LOAEL), a non-human study, and human variability. No MRLs are derived for acute oral exposures or for inhalation exposures of any duration.

Addendum to profile

A non-peer reviewed *Addendum to the Toxicological Profile for Polychlorinated Biphenyls* was developed by DTEM (now DTHHS) and released by ATSDR in April 2011 [ATSDR 2011]. The Addendum was not released for public comment prior to on-line publication. The purpose of the Addendum was to provide a supplement of the scientific data that had been published in open peer reviewed literature since the release of the profile in 2000. The Addendum did not propose any revisions to the MRLs for PCBs.

Interaction profiles

ATSDR has prepared several interaction profiles for toxic substances. These profiles address health and toxicology issues related to mixtures that are commonly found together and have similar modes of action of health effects in order to make recommendations on exposure assessment of potential hazards to public health. The interaction profiles are first released as a draft version for public comment and later as a final version.

PCBs are discussed in the *Interaction Profile for: Persistent Chemicals Found in Fish (Chlorinated Dibenzo-p-Dioxins, Hexachlorobenzene, p,p'-DDE, Methylmercury, and Polychlorinated Biphenyls)* [ATSDR 2004b]. The final version of this document was released in May 2004 and is available on the ATSDR website. The general recommendation was to treat this mixture as additive joint toxicity. There was some limited evidence to support PCB antagonism of TCDD (dioxin) immunotoxicity and TCDD developmental toxicity and synergism between PCB and methylmercury on neurological function and development.

PCBs are also included in the chemical mixture discussed in the *Interaction Profile for: Persistent Chemicals Found in Breast Milk (Chlorinated Dibenzo-p-Dioxins, Hexachlorobenzene, p,p'-DDE, Methylmercury, and Polychlorinated Biphenyls)* [ATSDR 2004a]. The final version of this document was released in May 2004 and is available on the ATSDR website. The neurodevelopmental deficits identified from exposures studies suggested an association with gestational rather than lactational exposure to these chemicals. As with the interaction of these chemicals from consuming contaminated fish, the recommendation was to treat this mixture as having additive toxicity for multiple chemicals.

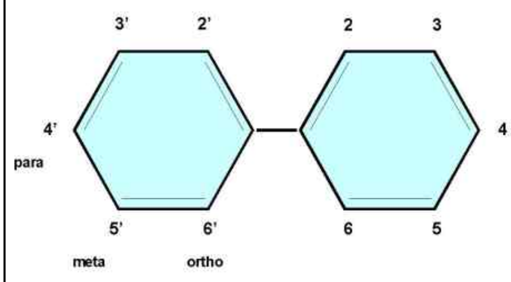
PCBs summary of health effects

The primary sources of information relied on to prepare this section summarizing health effects of PCBs were ATSDR's *Toxicological Profile for Polychlorinated Biphenyls (Update)* [ATSDR 2000], *Addendum to the Toxicological Profile for Polychlorinated Biphenyls* [ATSDR 2011], and *Public Health Implications of Exposure to Polychlorinated Biphenyls (PCBs)* [ATSDR 2002]. The latter is a briefing paper prepared jointly by ATSDR DTEM (now DTHHS) and EPA that summarizes the health implications associated with PCB exposure, primarily through fish consumption.

Evaluation of PCBs is complicated since they are found as a mixture of congeners that have individual toxicities and have interactions with each other. In general, the higher chlorinated PCB congeners are more resistant to metabolism and accumulate in tissues to a greater degree. Human epidemiological studies based on fish consumption are faced with competing health benefits from eating fish versus the adverse effects from PCBs.

Overview

Polychlorinated biphenyls (PCBs) refer to a group of man-made chemicals with a similar structure consisting of two bonded benzene (phenyl) rings surrounded by one to ten chlorine atoms (see figure below). There are 209 PCB congeners or structurally related molecules. With the exception of some research studies that isolate specific congeners for evaluation, generally, numerous congeners are found together. Some commercial mixtures are called Aroclors and are designated by the percent of chlorine in the mixture. Each mixture might consist of about 100 different congeners.



Structure of Polychlorinated Biphenyl (PCB) Molecule

Source: www.epa.gov

PCB molecules are extremely stable and tend to persist in the environment. In general, environmental persistence of the PCB congeners increases with the increasing number of chlorines on the molecule. They are very soluble in oil and insoluble in water. In the environment, PCBs, particularly the higher chlorinated congeners, are found mostly adsorbed to sediments or soil rather than in water.

Lower organisms may take up PCBs found in the sediment. At the successive levels of the food chain, the PCBs accumulate and become more highly concentrated in the organism; this is referred to as biomagnification. In higher organisms, such as fish, PCBs concentrate in the fatty tissue. The major dietary source of PCBs for humans is through the consumption of PCB-contaminated fish. Increased body burden is associated with increased fish consumption.

Toxicokinetics

Since PCBs are lipophilic, they are readily absorbed into the human body. For the general population, ingestion is the primary route of exposure. In the gastrointestinal tract, the PCB congeners enter the body by passive diffusion. Inhalation is considered the major route for occupational exposures. The dermal route is very time dependent and in most non-occupational scenarios does not appreciably contribute to the body burden.

Once absorbed in the body, PCBs have a biphasic distribution, with initial transport in the blood to the liver and muscle and later to the adipose tissue as the primary storage depot. In the blood, PCBs are carried on lipoproteins. Mobilization from adipose tissue can increase during pregnancy, lactation, or in periods with rapid weight loss.

The majority of PCBs undergo some biotransformation before being excreted in bile or urine. The liver is the primary site of metabolism. The first step is oxidation by the cytochrome P-450 system to form a hydroxylated PCB. The hydroxylated PCB may be further metabolized by hydroxylation or conjugation reactions. In general, the rate of metabolism decreases with the increasing degree of chlorination. The physiological half-life of the PCB congener can range from about half a year for a congener with three chlorines to nine years for PCB-209 which contains ten chlorines.

Mechanism of action

The mechanism of action of PCBs is complex because PCBs are found in mixtures which may have competing effects. Synergy has also been found with some combinations of PCB congeners. Some PCBs also share similar modes of action to other persistent chemicals such as dioxins and chlorinated pesticides. There are several proposed mechanisms of action of PCB congeners in the human body but they are often grouped into two major categories, aryl hydrocarbon (Ah) receptor dependent and independent mechanisms.

Co-planar PCB congeners (congeners without chlorine or with a single chlorine in an ortho position, which allows the rings to exist in the same plane) have a dioxin-like mechanism of action and bind with varying affinity to the Ah-receptor inside the nucleus. The Ah-receptor binding results in health effects through changes in gene expression. Animal studies show induction of some hepatic enzymes, body weight wasting, thymic atrophy, and porphyria.

The non-co-planar PCB congeners are associated with Ah-receptor independent mechanisms. These congeners induce phenobarbital-type hepatic enzymes. Animal studies have shown that there are both neurological and neurodevelopmental effects involving brain dopamine levels and calcium homeostasis that are related to the Ah-receptor independent mechanisms.

Some PCB effects are attributed to both the Ah-receptor independent and dependent mechanisms. These include liver hypertrophy, immune suppression, cancer, reproductive dysfunction, and thyroid hormone disruption. Some lower chlorinated non-co-planar PCBs are estrogen-like in their mechanism of action. These short lived PCBs interact with estrogen receptors and can potentiate estradiol activity.

Non-cancer health effects

While there are human health effects related to acute high exposures and exposures from inhalation, this section summarizes the primary health effects associated with chronic ingestion exposures for PCBs. Since the primary exposure pathway for humans is through ingestion of fish that have accumulated PCBs in their tissues, health effects related to consuming PCB contaminated fish are highlighted. The non-cancer health effects briefly discussed included developmental, reproductive, immunological, and endocrine effects.

Developmental effects

Developmental effects are the target of public health interventions associated with pre- and post-natal PCB exposure. Fetuses, infants, and children are considered sensitive populations to PCB exposures. PCBs cross the placental barrier and maternal PCB body burdens are mobilized during pregnancy and transported to the developing fetus. PCBs are stored in breast milk. Human body burden studies have shown correlations between fish consumption rates and breast milk PCB concentrations. Epidemiological studies in children suggest that health effects from *in utero* exposures may be more significant than from breast feeding. Fetuses and young infants generally lack developed liver detoxification mechanisms for PCBs.

PCBs are not known to cause structural birth defects, but influence neurobehavioral and developmental deficits. Multiple studies comparing infants of mothers who ate moderate to high amounts of Great Lakes

or other PCB-contaminated fish before or during pregnancy to those who did not eat fish have found neurobehavioral deficits such as abnormally weak reflexes, less responsiveness to stimuli, and greater motor immaturity. Follow-up studies and studies in children exposed to PCBs *in utero* have generally found that neurobehavioral deficits persist and children were more likely to have difficulty paying attention and to lag in verbal and other cognitive abilities.

Developmental effects from *in utero* PCB exposure found in human epidemiological studies include decreased birth weight, head circumference, and gestational age. Occupational studies of women exposed to PCBs in manufacturing jobs have found a decrease in birth weight and gestational age of their infants. Some human studies have not found this association. The range of results may reflect confounding contributions to these metrics, including the health benefits from eating fish.

Non-human primate studies have supported the developmental and neurobehavioral findings from human studies. A study on post-natal oral exposure to a PCB congener mixture in monkeys from birth to 20 weeks of age that looked at neurobehavioral endpoints was the basis for the derivation of ATSDR's MRL for intermediate oral exposure to PCBs [ATSDR 2000]. The congener mixture used in this study was considered comparable to that found in human breast milk. Learning response decrements were noted in the monkeys with PCB exposure.

<u>Reproductive effects</u>

Human studies are variable in respect to the association of PCBs with reproductive effects in adults. For example, an epidemiological study found modest association in Lake Michigan anglers with risk for conception failure in men, but not in women. Another study determined that decreased menstrual cycle length was associated with the number of fish meals. A cohort of girls exposed to PCBs in their diet suggested a decreased time to menarche. A study on time to menopause found no significant difference with PCB exposure. Non-human primate studies have demonstrated alterations in menstrual cycles, decreased fertility, and increased number of abortions in females exposed to PCBs.

<u>Immunologic effects</u>

The immune system was considered one of the more sensitive systems in the derivation of ATSDR's MRL for chronic oral exposure to PCBs. An ingestion study on immunological effects in Rhesus monkeys is the basis for the MRL [ATSDR 2000]. The study found significantly decreased IgM and IgG antibody levels when the animals were challenged at 23 months of PCB exposure. A similar trend was found at a challenge at 55 months. Studies of shorter duration on non-human primates support the role of PCB on immune function, with decreased antibody responses, increased infections, and histopathological changes in the thymus and spleen being reported.

Both studies on newborns exposed during pregnancy and experimental monkey studies have found a decrease in thymus size with PCB exposure. A study that looked at antibody response to childhood vaccinations found a decreased response with pre-natal exposure to PCBs. In another study, infant susceptibility to infections was found to be positively correlated to maternal serum PCB levels of mothers who consumed Great Lakes and Sheboygan River fish.

Endocrine effects

In addition to the endocrine related health effects reported in the reproductive effects section, studies have found impacts on other endocrine functions. Reductions in serum thyroid hormone levels in workers and in newborns exposed to PCBs during pregnancy have been reported. The latter finding in newborns is of interest because of the role of the thyroid in normal development of the brain. Studies on non-human primates and other experimental animals also support the role of PCB toxicity on thyroid hormones. Some more recent studies on fisherman cohorts and Great Lakes fish consumers support the association of type 2 diabetes mellitus and exposure to PCBs.

Cancer

The International Agency for Research on Cancer (IARC) classifies PCBs as group 2A, probably carcinogenic to humans (http://www.inchem.org/documents/iarc/suppl7/polychlorinatedbiphenyls.html). This category is generally used by IARC for a chemical when there is limited evidence of carcinogenicity in humans, but sufficient evidence in animals [IARC 2006]. Similarly, EPA has found sufficient animal studies, but less conclusive evidence from human studies, and classifies PCBs as group B2, a probable human carcinogen. The potential for PCBs to cause cancer increases with the degree of chlorination of the mixture or congener. Mixtures with greater than 50% chlorination have been found to have the strongest associations with cancer. The derivation for the ATSDR CREG value for PCBs uses EPA's oral upper-bound cancer slope factor 2 mg/kg/day, which is applied to scenarios that involve high-persistence or dioxin-like PCB exposures and dietary exposures.

Some occupational cancer mortality studies have reported increased mortality rates for various cancers including liver cancer, intestinal cancer, brain cancer, lymphoma, and melanoma. Other worker cohorts have not found an increased mortality risk for these cancers. Methodological limitations such as worker exposure classification and confounding risk factors may account for inconsistencies between studies. A recent population-based case control study found exposure to more highly chlorinated PCBs was associated with increased risk of non-Hodgkin's lymphoma. Animal studies have conclusively shown the association of PCBs and the induction of liver tumors.

Public Health Assessments (PHA)

PHA overview and process

A public health assessment (PHA) is a written, comprehensive, evaluation about the hazardous substance released at a site and the likelihood that exposure by inhalation, ingestion, or direct contact can or has occurred and if the level of exposure could result in harm. Generally, the PHA will examine multiple exposure pathways and chemicals of concern. The PHA process serves as a mechanism for ATSDR and the state health department cooperative agreement program partners to determine appropriate public health interventions.

ATSDR prepares a PHA for every site that is on or is proposed for listing on the National Priority List. The Agency may also prepare a PHA or health consultation at the request of EPA or other state or local agencies. ATSDR will also receive and review petitions from community groups or individuals and determine if a PHA is the most appropriate public health response.

ATSDR's *Public Health Assessment Guidance Manual* (updated) [ATSDR 2005] describes the methodologies that should be considered by health assessors in their evaluations of sites. As part of the PHA evaluation, environmental and health data are reviewed and community concerns are addressed. ATSDR does not typically collect its own environmental data, but reviews information from EPA or other governmental agencies. If a public health hazard is determined to be present at the site, recommendations are made for reducing or eliminating the exposure. ATSDR works with EPA and other state and local environmental and health agencies to ensure that the public health interventions can be implemented. Before the PHA becomes final, there is a public release of the document for community review and comment. A public meeting may also be held to discuss the findings and public health action plan.

Public health hazard categories

ATSDR public health hazard categories were established to ensure a consistent approach across hazardous waste sites evaluated. The categories are described in the ATSDR PHA guidance manual [ATSDR 2005]. Based on the analyses conducted in the PHA process, one of five conclusion categories are determined for each completed or potential exposure pathways identified for the past, present, and future exposures. A completed exposure pathway consists of a source of contamination, transport through an environmental medium, a point of exposure, a route of exposure, and a receptor population. The five elements may have occurred in the past or be presently occurring. A potential exposure pathway exists if at least one of the elements cannot be confirmed, but may have occurred in the past or may occur in the future.

The five public health hazard categories are:

1) Urgent public health hazard -- This category applies to sites with physical hazards or evidence of short-term (less than 1 year) exposure to site-related hazardous substances that may result in an adverse health effect among sufficiently exposed people and requires more immediate public health interventions.

2) Public health hazard -- This category applies to sites with some physical hazards or evidence of chronic (more than 1 year) exposure to site-related hazardous substances that might result in adverse health effects to sufficiently exposed people.

3) Indeterminate public health hazard -- This category applies to sites where critical information is lacking so no conclusion can be made.

4) No apparent public health hazard -- This category applies to sites with possible exposure to site-related hazardous substances but at concentrations or duration not likely to cause adverse health effects.

5) No public health hazard -- This category applies to sites where no exposure to site-related hazardous substances is occurring.

PHA Lower Fox River

Overview and document summary

The Wisconsin Department of Family Health Services, Division of Public Health, prepared the *Public Health Assessment for PCB Contaminated Sediment in the Lower Fox River and Green Bay, Northeastern Wisconsin, EPA Facility ID: WI0001954841* [ATSDR 2006] for the citizens of Northeastern Wisconsin and ATSDR. Wisconsin is part of ATSDR's cooperative agreement program and the PHA was prepared in accordance with ATSDR methodologies and guidelines. The ATSDR *Toxicological Profile for Polychlorinated Biphenyls (Update)* [ATSDR 2000] was one of the documents referred to in the section on toxicological implications of PCBs in the Lower Fox River. The *Baseline Human Health and Ecological Risk Assessment* prepared for the Wisconsin Department of Natural Resources (DNR) [WDNR 2002] as part of the remedial investigation and feasibility study for the site was cited in discussions on exposure pathways.

The final PHA for the site was released in March 2006. Prior to the final document, a public comment draft document was released in December 2001. EPA and Wisconsin DNR were provided the document for review and comment. All phases of PHA preparation underwent internal review by ATSDR.

The comments received from the various entities were incorporated into the final PHA. In addition to the inclusion of comment responses, the December 2001 public comment PHA differed from the final PHA in 2006 in that recommendations concerning clean-up were removed. In the interim period between the releases, EPA and Wisconsin DNR had adopted, and in 2004 started implementing, a clean-up plan for removing contaminated sediments from the river. The primary focus in the final PHA was directed at increasing awareness of fish consumption advisories.

The PHA addressed the issue of PCB contaminated sediment in the Lower Fox River from Lake Winnebago to the bay of Green Bay. A summary data table was included that presented PCB distribution in sediments in various sections of the Lower Fox River. During the late 1950's and 1960's, approximately 600,000 pounds of PCBs were released at the site, contaminating 11 million tons of sediment [ATSDR 2006]. The stretch from the De Pere Dam to the mouth of the river at Green Bay contains the most heavily contaminated sediments.

Because of accumulation of PCBs in the aquatic food chain, the public would be exposed to PCBs through ingesting fish caught in the river. The PHA reported that there are approximately 47,000 licensed anglers in the counties bordering the Lower Fox River [ATSDR 2006]. To help manage the non-cancer health risk from PCB exposures, fish consumption advisories have been placed on the river since 1976 [ATSDR 2006]. A table with the Wisconsin DHFS 2005 fish consumption advisories for the Lower Fox River was included in the PHA.

The PHA discussed both the efforts and outreach gaps in communicating the fish advisories to women, children, and various ethnic and minority groups. The Hmong ethnic group was specifically identified because of issues on written language and cultural cooking practices. The PHA reported that a 1997 U.S. Fish and Wildlife survey found that 80% of the 70 Hmong and Laotian anglers interviewed were eating fish caught from the river and 50% of all 120 anglers surveyed were eating fish included in the fish consumption advisories [ATSDR 2006].

Community members had concerns about past exposures to PCBs from eating contaminated fish before they had been aware of the advisories. Others felt health risks were overstated. Exposure pathways from contact with PCB contaminated sediments or surface water and inhalation of PCBs in air were also evaluated in the PHA to address community concerns.

Studies were cited in the PHA concerning both cancer and non-cancer health effects related to long-term exposure to PCBs. The non-cancer health effects briefly discussed included developmental and reproductive, immunological, neurological, and endocrine effects. A brief discussion about the interaction of multiple persistent chemicals in the fish was made in the document. Mercury levels in the fish in the Lower Fox River were not remarkably higher than in many other water bodies in Wisconsin [ATSDR 2006]. It was also stated that the relative risk from PCB in fish was so high that the risk estimates did not change substantially when the other contaminants were considered.

PHA conclusions and recommendations

The main conclusion from the PHA was that exposure from eating PCB contaminated fish from the Lower Fox River and Green Bay poses a public health hazard. While the fish consumption advisories had reduced the rate at which many residents ate the PCB contaminated fish, women and ethnic minorities were least likely to be aware of the advisories. Although the clean-up activities were proceeding, the fish consumption advisories on the river would be anticipated to be required for many years.

Wisconsin DHFS recommended continued and improved communication of the fish consumption advisories by other state and local health departments, especially to women and minority groups. DHFS also recommended continued monitoring of PCB levels in fish from the Lower Fox River and Green Bay and to adjust the advisories accordingly. The public health action plan presented actions previously undertaken, currently underway, and planned that demonstrated implementation of these recommendations.

The evaluations of the other pathways determined that the exposures to contaminated sediments from other uses of the river and Green Bay, such as wading, swimming, and boating, poses no apparent public health hazard. In the evaluation, both incidental ingestion of water during these activities and direct contact with contaminated sediment and water were considered. The exposure frequency, duration of exposure and dose were considered too low to result in an increased health risk.

Current status of Lower Fox River

Clean-up status

The Lower Fox River and Green Bay site was divided into five operable units (OUs) by Wisconsin DNR and EPA: OU 1 – Little Lake Butte des Morts; OU 2 – Appleton to Little Rapids; OU 3 – Little Rapids to De Pere; OU 4 – De Pere to Green Bay; and OU 5 – Green Bay. EPA completed the first Five Year Review of the Lower Fox River in July 2009 [EPA 2009]. The timing of the 5-year review was in relation to the initial implementation of the clean-up plan in 2004. The next 5-year review is expected in July 2014.

Remediation of PCB contaminated sediments in OU 1 began in 2004 and was completed in 2009, except for any long term monitoring. In 2011, the Wisconsin DNR issued a post-remediation executive summary

report on OU 1 [WDNR 2011]. Dredging removed about 370,000 cubic yards of PCB containing sediment [EPA 2009]. Monitoring performed in 2010 showed reductions of PCB concentrations in fish in OU 1. Post-remedy, 89% of the OU 1 walleye fillets tested fell below the 0.05 parts per million (ppm) threshold concentration used for unlimited fish consumption by Wisconsin and the PCB concentrations were 73% less than the concentration that would be expected from natural recovery [WDNR 2011].

According to the Superfund factsheet on the Fox River NRDA/PCB Releases (http://www.epa.gov/R5Super/npl/wisconsin/WI0001954841.html), remedial design work on OU 2 – 5 began in March 2004, and the dredging and capping work started in spring 2009. Prior to the full-scale clean-up of these operating units, a hot spot of 130,000 cubic yards of PCB-contaminated sediment just downstream of the De Pere Dam (in OU 4) was dredged in 2007. This area had some of the highest concentrations of PCBs in the river. Clean-up actions in OU 3 were completed in 2011. Monitored natural recovery was the selected remedy for most of OU 2 and OU 5 [EPA 2009].

Except for long-term monitoring and assuming clean-up operations remain on schedule, river clean-up, which will remove or contain a total of 8 million cubic yards of PCB-contaminated sediments, is anticipated to be completed by 2017. According to the Superfund factsheet on the site, as of January 2012, more than 2 million cubic yards of PCB-contaminated sediment had been dredged.

Fish consumption advisories

The state of Wisconsin continues to post fish advisories for the Lower Fox River due to PCB levels in fish. Fish advisories for these inland waters fall under the purview of the state and are reviewed and revised periodically based on trends in fish sampling results. The advisories are determined using the *Protocol for a Uniform Great Lakes Sport Fish Consumption Advisory* that was established by a consortium of public health and natural resource experts from eight Great Lakes states and Ontario, Canada [Anderson 1993].

A health protection value of 0.05 µg PCB/kg body weight/day was selected by the consortium using a "weight of evidence" approach that represented a composite of adverse health outcomes described in multiple studies [Anderson 1993]. Assuming a 70 kg adult would eat a ½ pound (227 gram) fish meal, the goal of the advisory was to keep the ingestion of PCBs from sport fish below 3.5 µg PCB per day [Anderson 1993]. The health protection value selected by the consortium and used by Wisconsin DNR in their five fish consumption advisory categories is two and one-half times greater than ATSDR's chronic oral MRL of 0.02 µg PCB/kg body weight/day.

The Wisconsin DNR factsheet on fish consumption advice for Green Bay and Lower Fox River Area of Concern (http://dnr.wi.gov/org/water/wm/foxriver/documents/GreenBay_FoxRiverAOC(2).pdf) and the Wisconsin DNR fish, "Eating Your Catch" fish advisory webpage (http://dnr.wi.gov/topic/fishing/eatyourcatch.html) provide recent updates for the Lower Fox River. The river advisories are split into two sections, the Fox River from Little Lake Butte des Morts downstream to the dam at De Pere and the Fox River from the De Pere Dam downstream to the mouth where it enters Green Bay. The advisories list the maximum number of fish meals per time period that men and older women or women of childbearing age and children under 15 are advised to eat by game fish species found in the Lower Fox River. The advisories include information on preparing and cooking fish meals.

There have been several changes in the fish advisories when the latest version is compared to the table provided in the 2006 Lower Fox River PHA. For the section of the Lower Fox River from Little Lake Butte des Morts downstream to the dam at De Pere, channel catfish, bluegill, crappie, sunfish, and "all other gamefish" have been added to the advisory with various restrictions on consumption up to "eat no more than one meal per month." The inclusion of these new species may reflect increased awareness from more extensive recent sampling; prior sampling may not have been conclusive enough to include the species in the advisory. All sizes of smallmouth bass appear under "eat no more than one meal per month" on the 2005 advisory, but would currently be included under "all other gamefish." The "do not eat" advisory for carp and the "eat no more than one meal per month" advisory for all sizes of northern pike, walleye, white bass, white perch, and yellow birch have not changed since 2005.

The fish advisories for the section of the Lower Fox River from the De Pere Dam downstream to the mouth where it enters Green Bay have shown some improvement, with the length of fish for sheepshead and walleye being less restrictive for the "eat no more than one meal per month" through "do not eat" recommendation categories. The advisory for eating all sizes of white sucker has changed from once a month from every two months. All sizes of big-mouth buffalo is now included in the "do not eat" category, but was not listed in 2005. The size category recommendations for northern pike remain unchanged. The remainder of the fish on the advisory remains unchanged since 2005, with the recommendation for eating all sizes of other fish species being "eat no more than one meal per month."

Conclusions

After review of the 2006 PHA on *PCB Contaminated Sediment in the Lower Fox River and Green Bay, Northeastern Wisconsin* [ATSDR 2006] and health information related to PCBs, I concur with the conclusion in the PHA that ingestion of PCB-contaminated fish poses a public health hazard. Given the current fish advisories and site clean-up status, this completed exposure pathway still exists. Eating PCB-contaminated fish is a major source of PCBs to residents in the non-occupational setting and is the most significant pathway of exposure to residents in the Lower Fox River area. The conclusion of a public health hazard from eating contaminated fish from the Lower Fox River is still relevant today.

The no apparent public health hazard determination for the other routes of exposure to PCBs from the sediment, *i.e.* from direct contact with sediment, drinking surface water with particles of disturbed PCB-containing sediment, or inhaling PCBs volatilizing from sediment, is a reasonable conclusion.

Fish eaters and other epidemiological studies, as well as animal studies, have demonstrated a range of health effects from PCBs. PCBs from eating fish will accumulate in the body. The most susceptible populations for exposure to PCBs are fetuses, infants, and young children who may acquire PCBs during gestation, lactation, or eating fish. The studies that examined infants and children of mothers who were fish eaters are particularly relevant, since associations have been found with neurobehavioral and developmental deficits in this group even after controlling for other risk factors and the positive effects from a fish diet.

Some of the PCB epidemiological studies compared adverse effects on groups of people within categories of exposure such as number of fish meals. While this information may not be directly transferable in terms of predicting an individual's health outcome, it is a useful measure at the community level. ATSDR

and Wisconsin DHFS practice on the community level and their scope is protecting the public. Making recommendations based on limiting fish meals to prevent adverse health outcomes is a practical approach for reducing harmful exposures.

While fish consumption advisories are an important communication tool aimed at reducing the body burden of PCBs by discouraging exposure, advisories are not enforceable and are often not heeded by the public. For risk management of exposure to hazards, generally, interventions that require active participation and adherence by those at risk are ranked low on the hierarchy of controls. The advisories not only have to be communicated to individuals and the health education messages reinforced regularly, but they need to be accepted and acted upon by those individuals. The 2006 PHA pointed out that although the advisories have been in place on the Lower Fox River since 1976, studies had found certain groups were either not aware of the advisories or did not adhere to them.

Advisories have to balance the health message of the benefits of eating fish, which provides a diet high in protein and low in saturated fats, versus the adverse health effects associated with eating PCB-contaminated fish. Thus, in an effort to not completely discourage people from eating a fish diet and provide people with information on fish options that contain less PCB contamination, the advisories become complicated. The advice is listed by species and size, include recommendations ranging from unrestricted to never eating, and vary if a person is a man or a woman beyond childbearing years or not. The advisories also may conflict with cultural differences on fish preparation and the competing need by subsistence fisherman to consume this inexpensive food source.

The Wisconsin DNR post remedial executive summary report on OU 1 provided information on PCBs in fish tissue that showed that the dredging remedy appeared more effective than natural recovery in reducing the concentration of PCBs in fish [WDNR 2011]. Based on on-going sampling results from the Wisconsin DNR, fish advisories of the Lower Fox River are still warranted. These fish consumption advisories should be considered an interim and insufficient measure for attempting to reduce the public's exposure to PCBs. Thus, with the long-term objective of reducing exposure to the public, continued clean-up of the PCB sediments would be in the public interest.

Works Considered

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Statement regarding compensation and prior expert testimony

I am receiving no compensation for the preparation of this report or for any testimony I may provide in this matter other than my salary provided by ATSDR since I am serving as an expert as part of my official federal government duties.

I have not provided an expert report nor have I been an expert witness in any other proceeding.

Curriculum Vitae (attached)

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September 7, 2012